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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/687,373	10/16/2003	James M. Chen	263.PC2	9295
25000	7590	10/14/2005	EXAMINER	
GILEAD SCIENCES INC 333 LAKESIDE DR FOSTER CITY, CA 94404			RAHMANI, NILOOFAR	
			ART UNIT	PAPER NUMBER
			1625	

DATE MAILED: 10/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/687,373

Applicant(s)

CHEN ET AL.

Examiner

Niloofer Rahmani

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 July 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-55, 58, 63 and 80 is/are pending in the application.
- 4a) Of the above claim(s) 64-70 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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### DETAILED ACTION

1. Amendment and response filed by applicant's date 07/05/2005 has been entered and considered carefully. Claims 1-55, 58, 63, 80 are pending. Claims 64-70 are withdrawn. Claims 56-57, 59-62, and 71-79 are cancelled.
2. The rejection of claims 1-15, 18-21, 23-31, 35-44, 49-52, 54-55, 58, 63-70 under 35 U.S.C. 112, second paragraph is maintained for reason of record.

The definition of Ar in the specification on the pages 4 and 18 is very confusing. On the page 4, Ar is selected from C<sub>3</sub>-C<sub>12</sub> carbocycle, and on the page 18, Ar is defined as heterocycle C<sub>3</sub>-C<sub>12</sub> ring atoms. On the page 4, Ar is selected from C<sub>2</sub>-C<sub>20</sub> heteroaryl, and on the page 18, Ar is defined as C<sub>2</sub>-C<sub>6</sub> is three ring member must be saturated. Therefore, the definition of Ar is unclear. It is recommended that the Ar group explicitly disclosed on the pages 4 and 18 is incorporated into the claims.

The term "a prodrug moiety" as now amended is confusing. Please, note prodrug must be pharmaceutically acceptable since this is how such concept works (See Design of Prodrugs Handbook, Chapter 1). Attorney's argument that prodrugs are useful as intermediates has no scientific basis for such concept.

### 3. ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Newly amended, claim 49 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The specification lacks a written description of the claimed definition for term "P". There is no antecedent basis in the specification for "P".

4. The rejection under 35 U.S.C. 101 of the claims 22,45, 48 is maintained over the claims 22,45, 48 of copending Application No. 10/687374. Please, note all identical compounds in the two sets of claims.

5. Obvious double patenting rejection of the claims 1-21, 23-44, 46-47, 49-63,68,80 over claims 1-21, 23-44, 46-47, 49-63, 68 of copending Application No. 10/687374 is maintained. Although the conflicting claims are not identical, they are not patentably distinct from each other because the current invention embraces the invention claimed in the above conflicting application.

Determination of the scope and content of the prior art (MPEP §2141.01)

Chen et al. Application No. 10/687374 claimed compounds and compositions in the claims 1-21, 23-44, 46-47, 49-63, 68 as the same structural core formula with subset of Markush elements as the instant claims.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the instant claims and the copending claims 1-21, 23-44, 46-47, 49-63, 68 is that the instant claims are fully embraced by the

copending claims, when Y-Z is  $\text{c}=\overset{\text{R}'}{\text{C}}$ .

Finding of prima facie obviousness-rational and motivation (MPEP §2142.2143)

The claims of the instant application and copending application contain enormous amount of overlapping subject matter. The overlapping subject matter is the result of the mix and matching the Markush elements from the broad scope. Mix and matching of Markush elements are considered prima facie obvious.

This is provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

**The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 168 USPQ 644 (CCPA 1969).**

**A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130 (b).**

**Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).**

**6. THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

**7.** Any inquiry concerning this communication or earlier communications from the examiner should be directed to Niloofar Rahmani whose telephone number is 571-272-4329. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or public

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PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

NILOOFAR RAHMANI

10/12/2005

N.R.



CELIA CHANG

PRIMARY EXAMINER

GROUP 1625